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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/813,449

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Enrique J. Klein

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7612

57360

7590

05/27/2010

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EXAMINER

DOWE, KATHERINE MARIE

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

05/27/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/813,449	Applicant(s) KLEIN ET AL.	
	Examiner KATHERINE M. DOWE	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-14,16-20,23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-14,16-20,23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/28/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 28, 2010 has been entered.

2. Claims 1, 2, 5-14, 16-20, 23, and 24 are currently pending.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 5 recites the limitation "the another needle" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1, 2, 5-14, 16-20, and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Gordon (US 5,364,408). Gordon discloses a method for

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suturing tissue in the proximity of an aperture in a tissue wall comprising positioning distal-most ends of a suture (4) distally of the aperture of the tissue wall (Fig 1a), advancing first and second needles (6) from a distal side of the tissue wall into a guide body (16) of the suture applying device (Figs 1a-1c) to form a port within the tissue wall (Fig 1d) in proximity of the aperture and drawing at least a portion of the suture from the distal side of the tissue wall to the proximally through the port in the tissue wall (Figs 1d-1g), and forming a loop with the remaining portion of the suture to secure the suture (Figs 1a-1h; col 6, ln 48-col 7, ln 9). The needles and suture are advanced by advancing a shaft (32) that supports the needles on its distal end through the aperture.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon (US 5,364,408) in view of Lee (US 5,292,332). Gordon discloses the invention substantially as claimed including a method for suturing tissue in the proximity of an aperture comprising advancing a suturing device having a distal end and flexible sheath (32) extending therefrom through the aperture in the tissue wall, the suturing device positioning distal-most ends of a suture (4) distally of the aperture in the tissue wall (Figs 1a-1b), passing at least one needle (6) and at least one portion of a suture (4) from the distal side of the tissue wall, and forming a loop with the suture to secure the suture (Figs 1a-1h; col 6, ln 48-col 7, ln 9).

However, Gordon does not disclose a guidewire extends through an aperture in a tissue wall. Lee discloses a method for sealing an aperture in a tissue wall (14) and teaches a guidewire (18) extends through an aperture in the tissue wall such that the sealing device (22) may be guided along the guidewire to the target site at the aperture (Figs 3-6; col 5, ll 15-23). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Gordon such that a guidewire extended through the aperture in the tissue wall to guide the suturing device through the aperture and simplify the procedure.

Response to Arguments

11. Applicant's arguments, see amendment, filed January 28, 2010, with respect to the rejection(s) of claim(s) 1, 2, 5-14, 16-20, 23, and 24 under Sauer et al. (US 5,368,601) have been fully considered and are persuasive. Applicant argues Sauer et al. do not disclose advancing the needle into a guide body of the suture applying device after passing the needle through the tissue. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Gordon (US 5,364,408).

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe
May 19, 2010

/K. M. D./
Examiner, Art Unit 3734

/TODD E. MANAHAN/
Supervisory Patent Examiner, Art Unit 3734